IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

METACEL PHARMACEUTICALS, LLC, *Plaintiff*, v. **RUBICON RESEARCH PRIVATE LIMITED**, *Defendant*.	Civil Action No. 2:21–CV-19463-EP-JRA *Document Filed Electronically*

PLAINTIFF METACEL PHARMACEUTICALS, LLC'S OPENING CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's Scheduling Order (Dkt. No. 25) and the Court's local civil rules, Plaintiff Metacel Pharmaceuticals, LLC ("Metacel"), submits its brief in support of its proposed claim term construction for the one disputed claim term of U.S. Patent No. 10,610,502 ("the '502 Patent"). Also, filed herewith is the declaration of Dr. David Savello ("Savello Decl."), containing his initial opinion regarding the construction of the disputed claim term.

I. INTRODUCTION

Metacel presently contends that Rubicon infringes claims 1 and 2 of the '502 Patent issued on or about April 7, 2020, entitled "Oral Baclofen Solutions" based on Metacel's understanding of the information currently available to Metacel regarding Rubicon's Accused Instrumentality identified below. Rubicon did not provide all sample products and materials that Metacel has requested from Rubicon and Metacel's present understanding may be modified after testing of these products and materials, to the extent these materials can be obtained for testing and were not improperly destroyed or disposed of by Rubicon.

Consistent with Federal Circuit law, Metacel's construction of the one term in dispute employs the ordinary and customary meaning as understood by a scientist that mirrors the plain language in the claims and the patents' written

description known as the "specification." The parties dispute the construction of "a buffer comprising citric acid, a salt of citric acid, or any combination thereof." Metacel contends that this term should be construed as a "substance capable of neutralizing both acids and bases in solution and thereby resisting a change in pH of the solution; also a solution containing such a substance wherein the solution contains citric acid, citric acid salts, or combinations thereof." "There is a heavy presumption that claim terms are to be given their ordinary and customary meaning." *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1358 (Fed. Cir. 2017) (quoting *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013)); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (claim construction typically applies the ordinary and customary meaning as understood by a person of skill based on the intrinsic record). Metacel's ordinary and customary constructions rest firmly in the intrinsic record and Federal Circuit law on claim construction.

To try to avoid infringement, Defendant seeks to improperly construe and parse a singular claim term to restrict the scope of Metacel's patents or have them outright adjudicated to be invalid in view of the prior art. Rubicon does not challenge any claim term under 35 U.S.C. § 112, yet the Court should find Rubicon's proposed construction disfavored for potentially creating an indefiniteness issue.

As Judge Chesler noted in another patent case where a defendant sought to employ similar tactics on claim construction: "[Defendant] follows a path well-worn by patent challengers, and Federal Circuit law disfavors this path." *Curlin Med. Inc. v. Acta Med., LLC*, 228 F.Supp.3d 355, 361 (D.N.J. 2017) (emphasis added). Likewise, Defendants well-worn path finds disfavor in the Federal Circuit law, in which Defendants seek to avoid infringement by improperly limiting certain claim terms to specific embodiments disclosed in the patent's specification, in violation of Federal Circuit authority. *Phillips*, 415 F.3d at 1323 (error to limit claims to specific embodiments).

Metacel's straightforward construction employs the ordinary and customary meaning as understood by one of skill, mirrors the plain language in the claims and the specification, is anchored in Federal Circuit precedent. Metacel requests that its ordinary and customary construction be adopted, Defendant's flawed constructions be denied, and any indefiniteness or other affirmative defenses that may arise be denied and/or deferred until summary judgment or trial.

II. FACTUAL BACKGROUND AND THE PATENTED TECHNOLOGY

Metacel presently contends that Rubicon infringes claims 1 and 2 of the '502 patent issued on or about April 7, 2020, entitled "Oral Baclofen Solutions" based on Metacel's understanding of the information currently available to Metacel

regarding Rubicon's ANDA Product.

a. Claims 1 and 2 of the '502 Patent

The asserted claims of the '502 patent are set forth below:

1. A method of relaxing muscles or treating spasticity in a subject in need thereof comprising administering to the subject an effective amount of an aqueous oral solution comprising (i) baclofen, (ii) a buffer comprising citric acid, a salt of citric acid, or any combination thereof, and (iii) optionally one or more preservatives, wherein prior to the administration, the amount of 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4-chlorophenyl) butanoic acid in the oral solution is determined to be below a threshold level and the oral solution is stored after the determination, but prior to the administration, at from about 2 to about 8° C.

2. The method of claim 1, wherein the threshold level is 0.2%.

b. The '502 Patent Specification

The '502 Patent is titled "Oral Baclofen Solutions" and is directed to baclofen-containing formulations, along with a detection protocol for detecting one or more impurities associated with the production of baclofen in the manner described in the '502 Patent specification. The '502 Patent also describes the use of

various baclofen solutions for treatment of conditions including relaxing muscles or treating spasticity. The '502 Patent specification discloses embodiments comprising a buffer and those defined as "buffer-free" as that term is used in the context of the specification. The '502 Patent also relates to "an assay for determining the amount of an impurity, such as 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4-chlorophenyl)butanoic acid, in a baclofen containing solution, and to methods of treatment using such aqueous oral solutions."

More particularly, the specification discloses the use of ion-exchange chromatography to determine the presence of the aforementioned impurity or the like, or quantity thereof (ion pair chromatography – Col. 2, Lines 1-5). The '502 Patent solved a shortcoming in the prior art related to measuring certain impurities contained in baclofen solutions, which was a result of methylparaben co-eluting with the impurities using conventional reversed-phase high performance liquid chromatography (HPLC). The prior art analysis cannot be used to determine the claimed impurity (4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4-chlorophenyl)butanoic acid and similar impurities (*see* Col. 1, Lines 47-52)). The '502 Patent also discloses that the ion-exchange chromatography is performed with an alkyl sulfonate (Col. 7, Lines 65-67), which is also known as an alkyl sulfonic acid. Further, the alkyl functional group identified by the '502 Patent refers to any

organic functional -R group, where R satisfies the chemical formula C_nH_{2n+1}, and the smallest possible alkyl sulfonic acid is methanesulfonic acid, which can be identified by the inventive assay method described in the '502 Patent.

c. The Prosecution History of the '502 Patent

The '502 Patent issued from U.S. Application 16/556,893 ("the '893 application"). The '893 application was filed on 30 August 2019. The '893 application originally consisted of 32 claims. Claims 1 – 10 claimed oral solutions of baclofen, which included a buffer. Claims 11 – 24 consisted of various method claims wherein the oral solution included a buffer. Claims 25 and 26 issued as claims 1 and 2 of the '502 Patent, claiming a method of relaxing muscles or treating spasticity. Claims 27-32 were directed toward solutions of baclofen characterized as buffer-free.

On October 28, 2019, the U.S. Patent Examiner issued a restriction requirement for the pending claims as follows:

> I. Claims 1-10, drawn to an aqueous solution, classified in A61K 31/195.
>
> II. Claims 11-12, drawn to a method of dispensing to a patient, classified in A61K 9/06.
>
> III. Claims 21 and 25-26, drawn to a method of relaxing muscles, classified in A61K 47/10.

The Examiner based the restriction requirement on the following rationale(s):

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially distinct method if using said product, such as product safety testing.

Inventions II and III are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a different function and design. Groups II recites active steps not required by Group III, such as storing the solution prior to dispensing and Group III requires oral administration of the solution which is not required by Group II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Notably, the Examiner did not base the restriction (i.e., inventive distinction) on buffered versus buffer-free claims. Although the applicant (Metacel) elected Group III (pending claims 21, 25, and 26), the applicant did so with traverse and requested that all claims '893 application be examined. As set forth in the Examiner's Notice of Allowability, the Examiner did not grant the applicant's traversal, on the basis that Groups II and III would require additional consideration under 35 USC § 112(a).

On January 20, 2020, the Examiner initiated an interview with the applicant, and summarized the substance of that interview as follows:

The Examiner contacted Mr. Lessler to discuss allowable subject matter. The Examiner explained that claim 25 was allowable due to the step of determining the amount of the 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4- chlorophenyl)butanoic acid as the prior art was silent regarding this impurity. However claims 1-12 and 21 lacked this step and would need to be canceled. Mr. Lessler agreed to the changes proposed by the Examiner..

On January 21, 2020, the Examiner issued the Notice of Allowability as to claims 25 and 26. The Examiner stated the reason for allowance as follows:

> The instant claims are directed to a method of relaxing muscle or treating spasticity in a subject, comprising the administration of an aqueous oral solution of baclofen, a buffer and optionally a preservative to a person in need thereof. Furthermore, prior to administration of the oral solution, the amount of 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4- chlorophenyl)butanoic acid, which is an impurity that results from the reaction between baclofen and the claimed buffers, in the solution must be determined and the solution then stored at 2-8°C.
>
> This closest prior art is Fallin (WO 2018/049184) who discloses aqueous oral solutions and suspensions of baclofen and buffers, such as sodium citrate (reading on a salt of citric acid) (Abs). These formulations are stable for at least 3 days when stored at 2-8°C (Pg. 4). Fallin also teaches that baclofen is a known muscle relaxer and antispastic agents often used to treat muscle symptoms (Pg. 7). However, Fallin is silent to the step of determining the amount of 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4- chlorophenyl)butanoic acid present in the oral solution. Fallin nor the prior art in general discuss the presence of 4-(3-carboxymethyl)-3-hydroxy-2,5-dioxopyrrolidin-1-yl)-3-(4-chlorophenyl)butanoic acid in solutions containing baclofen and the claimed buffers, thus there is no motivation or suggestion in the art to perform this step prior to the storage and administration of the oral solution.

Although the Examiner denied the entry of additional claims following the Notice of Allowability, claims 1 and 2 of the ’502 Patent issued as set forth in the patent.

III. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

Claim construction is ultimately a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

The Federal Circuit in the *en banc* Phillips case and other authorities sets forth the basic canons of claim construction. It is a "bedrock principle" of patent law that the claims of a patent define the invention. *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 111, 115 (Fed. Cir. 2004)). Claim construction "begins and ends in all cases with the actual words of the claim." *Google LLC v. Network-1 Techs., Inc.*, 726 Fed. Appx. 779, 785 (Fed. Cir. 2018) (quoting *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1375 (Fed. Cir. 2017)). "There is a heavy presumption that claim terms are to be given their ordinary and customary meaning." *Aylus*, 856 F.3d at 1358 (quoting *Aventis*, 715 F.3d at1373); *see also Wasica*, 853 F.3d at 1281 ("It is axiomatic that we will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history." (quoting *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333 (Fed. Cir. 2013))).

Thus, "absent a clear disavowal or alternative lexicography by a patentee, he or she is free to choose a broad term and expect to obtain the full scope of its plain

and ordinary meaning." *Wasica*, 853 F.3d at 1282 (quoting *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012)). The disavowal "must be ***clear*** . . . ***and cannot draw limitations into the claim from a preferred embodiment***." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357-58 (Fed. Cir. 2006) (emphasis added), citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

Claims do not stand alone. "'[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning' of terms in a claim." *Wasica*, 853 F.3d at 1288 (quoting *ACTV Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003)); *Phillips*, 415 F.3d at 1314 ("To begin with, the context in which a term is used in the asserted claim can be highly instructive.").

The ordinary and customary meaning should be determined from the viewpoint of a person of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312-13. The ordinary meaning of a term cannot, however, be construed in a vacuum; rather, the Court must look at the ordinary meaning in the context of the intrinsic evidence of record, *i.e.*, the language of the claims, the specification, and the patent's prosecution history. *Id*. at 1315, 1317. "Such intrinsic evidence is the most significant source of the legally operative meaning of the

disputed claim language." *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004); *see also Phillips*, 415 F.3d at 1313-17.

While claims must be examined in light of the specification, limitations may not be read into the claims from the patent's specification. *Anchor Wall Sys. Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306 (Fed. Cir. 2003). Although these two tenets may seem contradictory, the Federal Circuit has clarified that "[w]hile that task may present difficulties in some cases, we nonetheless believe that attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification." *Phillips*, 415 F.3d at 1323-24.

Indeed, the Federal Circuit has "repeatedly warned against confining the claims to those embodiments" described in the specification. *Id.* at 1323. In particular, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id*.

In addition, a court may also consider "extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Novartis Pharms. Corp. v. Par Pharm., Inc.*, No. CV 14-1494-RGA, 2015 WL 7566615, at *1 (D. Del. Nov.

23, 2015) (citing *Phillips*, 415 F.3d at 1317-19). Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id*.

IV. ARGUMENT

Construction of "a buffer comprising citric acid, a salt of citric acid, or any combination thereof" (the '502 Patent, Claim 1)

Metacel's Proposed Construction	Rubicon's Proposed Construction
"A substance capable of neutralizing both acids and bases in solution and thereby resisting a change in pH of the solution; also a solution containing such a substance wherein the solution contains citric acid, citric acid salts, or combinations thereof."	"a component of the oral solution that maintains the pH, which must include at least citric acid or a salt of citric acid"

The ordinary and customary meaning of "buffer comprising citric acid, a salt of citric acid, or any combination thereof" would have been understood by the skilled artisan to mean "a substance capable of neutralizing both acids and bases in solution and thereby resisting a change in pH of the solution; also a solution containing such a substance wherein the solution contains citric acid, citric acid salts, or combinations thereof." Indeed, this is the interpretation of a buffer under its well-understood function in chemistry, and one properly ascribed to the disputed claim term. *See* Savello Decl. at ¶¶ 28-29.

The specification provides examples of types of buffers that operate within oral solutions like those of the invention. Specifically, the specification recites a

"[b]uffer [that] comprises citric acid, sodium citrate or a combination thereof." (The '502 Patent at col. 2, ll. 58-64). The specification also refers to "another embodiment," where in "any of the aqueous oral solutions containing a buffer described herein, the buffer is a phosphate buffer, such as sodium phosphate." *Id*. Therefore, while the specification does not establish a meaning for "buffer" that differs from the ordinary and customary meaning, it evidences that, while claim 1 recites a specific buffer, the invention includes a buffer for its *function* of buffering.

The meaning of buffers would be well-understood by the skilled artisan to mean that buffers function to resist a change in pH when in solution, by neutralizing both acids and bases. (Savello Decl. at ¶ 26 ("A substance capable in solution of neutralizing both acids and bases and thereby maintaining the original acidity or basicity of the solution; also a solution containing such a substance.")). In view of this definition, it would have also been understood that a buffer can comprise multiple components, and a skilled artisan would have understood the portion of the solution with buffering capacity to be a buffer.

Rubicon's construction attempts to improperly narrow the meaning of the disputed claim term at least as a result of inclusion of the phrase "maintains the pH." This is because Rubicon's usage of this phrase truncates the definition and function of a buffer (which functions to resist change in pH in the presence of an

acid or a base) and ignores the fact that buffers typically do not maintain a pH at a static state, as demonstrated by the titration curve of buffer. *See id*. at ¶¶ 23-25. In fact, the evidence cited by Rubicon supports that a buffer resists pH change, rather than maintaining it. *Id*. at ¶ 27. While evidence cited by both parties refer to the maintenance of pH, the maintenance of pH occurs in the presence of an acid or base in the solution, but this maintenance of pH is not absolute. The skilled artisan would understand that a buffer does not, nor is it intended to, maintain a pH as set forth in Rubicon's construction because, at some amount of addition of an acid or a base, the buffer can no longer resist the change, and larger pH changes will ensue, leading to the titration curves associated with solutions with buffering capacity. *Id*. at ¶¶ 23-25. Rubicon's construction thereby misconstrues and improperly attempts to narrow the well-understood function of a buffer.

Rubicon's construction also imparts ambiguity. As construed by Rubicon, the disputed claim term could be interpreted to mean that the claimed oral solution contains a component that maintains pH ***and*** separately includes at least citric acid or a salt of citric acid, or combinations thereof. The disputed claim term recites that the "buffer compris[es] citric acid, a salt of citric acid, or any combination thereof" thereby indicating that the entire claim term refers to one thing: a buffer. It is also true that a buffer can function as a singular unit that can comprise subparts from different ingredients of a solution, which function as whole to provide buffering

capacity to a solution. This interpretation is confirmed by the definitions contained in chemistry textbooks as well, which refer to multiple solutes in solution that can function as a buffer: "The solutes responsible for this resistance to change in pH, or the solutions themselves are known as *buffers*." (Savello Decl. at ¶ 23 (citing Exhibit 2), ¶ 27. But, it is not clear how Rubicon's construction demarcates the boundaries around the buffer in reference to the other components of the oral solution, nor how the buffer functions in solution. As such, the Court should reject Rubicon's construction of the disputed claim term.

V. CONCLUSION

For the reasons explained above, Metacel respectfully requests that the Court adopt Metacel's proposed construction of the disputed claim term and deny Rubicon's.

Dated: October 14, 2022

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